

REMARKS

I. STATUS OF THE CLAIMS

After amendment, claims 1-5 and 9-13, 17, 20-21 are pending. Without prejudice or disclaimer, claims 6 and 14 are canceled herein. Accordingly, Applicants respectfully submit that no issue of written description is raised by these amendments

II. EXAMINER INTERVIEW

Applicants thank Supervisor Richter and Examiner Fisher for granting an in-person interview on January 6, 2010. Applicants agree with the Examiner Interview Summary dated January 12, 2010. Briefly, the rejections of all pending claims under 35 U.S.C. § 103 over *Tessari* (U.S. PGPUB No. 2002 0077589) in view of *Osman et al.* (WO 00/72821) ("*Osman*") were discussed. It was agreed that after receiving a declaration that contained the comparative data from the *Eckmann et al.* study, submitted on March 16, 2009, the Office "will allow the case." See Interview Summary, dated January 12, 2010. The substance of the interview is captured in this response.

III. DECLARATION OF DAVID WRIGHT

As requested by the Office during the Examiner Interview conducted January 6, 2010, Applicants herein submit a declaration from inventor Dr. David Wright in further support of Applicants' arguments presented in the Amendment and Reply under 37 C.F.R. § 1.114, filed December 3, 2009. As previously discussed, the declaration describes a study published as *Eckmann et. al.*, Microvascular Embolization Following Polidocanol Microfoam Sclerosant Administration, *Dermatol. Surg.* 31: 636-43 (2005).

The *Eckmann et al.* study reports a side-by-side comparison in rats of (1) an air based foam, (b) a foam with 7% nitrogen, and (c) a foam with 0.01-0.8% nitrogen demonstrating that a foam with a nitrogen gas concentration within the claimed range shows unexpected results. See *Wright* declaration, attachment A.

Eckmann et al. injected each foam into the femoral artery of the rat and measured the number and size of the gas bubbles in the cremaster arterial microcirculation. *Wright* declaration, attachment A at ¶7. In addition, the authors observed gas bubble behavior (e.g., whether the bubbles blocked the arteries and if they did, how fast they cleared). *Id.*

As explained by Dr. Wright, the *Eckmann et al.* study surprisingly demonstrated that the 0.01-0.8% nitrogen foam displayed distinct differences from the 7% nitrogen foam. *Id.* at ¶12. Moreover, these differences render the 0.01-0.8% nitrogen foam safer than the 7% nitrogen foam. *Id.* at ¶13.

Therefore, Applicants have, as requested by the Office, submitted a side-by-side comparison of foam with a nitrogen content within the claimed range (0.01-0.8% nitrogen) with a foam taught by *Osman*, demonstrating the unexpected results of the instant foam. Therefore, Applicants have rebutted any *prima facie* case of obviousness.

V. CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: January 29, 2010

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Attachment:

A. *Wright, D.* declaration, January 20, 2010.